

## **REMARKS**

### **Claim Amendments:**

Claim 37 has been canceled, without prejudice or disclaimer. Applicants specifically reserve the right to file appropriate continuing and/or divisional application(s) drawn to the subject matter of this claim.

Claims 1-4, 7, 8, 10 and 21 have been amended; new Claim 38 has been added. Claim 1 has been amended to clarify that the claimed methods are used to treat inflammatory and neurological disorders. Claims 1, 4, 7, 8, 10 and 21 have been amended to clarify that the polypeptide fragments useful in the claimed methods comprise at least one D1, D2, D3, D4 or D5 domain of RHAMM. Claims 2 and 3 have been amended to correct dependencies based on the amendment of Claim 1.

New Claim 38, dependent from Claim 1 and drawn to methods of treating diabetes mellitus, has been added.

No new matter has been added by these amendments. The Examiner is hereby requested to enter these amendments.

### **Restriction Requirement:**

The Examiner has restricted the claims of this application into 10 groups, as follows:

- I. Claims 1-10 and 21-24, drawn to a method for treating a patient with a distinct type of inflammatory neurological disorder, where the disorder is (i)

Parkinsons disease, (ii) Alzheimer disease, (iii), arthritis, (iv) multiple sclerosis, (v) inflammatory dermatosis, (vi) inflammatory bowel disease and (vii) inflammatory lung disease, are classified in class 514, subclass 2<sup>+</sup>, class 530, subclass 300 and 387.1, class 436, subclass 86, class 435, subclass 7.1, 320.1 and 325.

- II. Claims 11-18, drawn to a method for treating a patient with wounds, are classified in class 514, subclass 2<sup>+</sup>, class 530, subclass 300 and 387.1, class 436, subclass 86, class 435, subclass 7.1, 320.1 and 325.
- III. Claim 19, drawn to a method for treating cancer, are classified in class 514, subclass 2<sup>+</sup>, class 530, subclass 300 and 387.1, class 436, subclass 86, class 435, subclass 7.1, 320.1 and 325.
- IV. Claim 20, drawn to a method for treating kidney fibrosis, are classified in class 514, subclass 2<sup>+</sup>, class 530, subclass 300 and 387.1, class 436, subclass 86, class 435, subclass 7.1, 320.1 and 325.
- V. Claim 25, drawn to a method for treating obesity and obesity related disease, are classified in class 514, subclass 2<sup>+</sup>, class 530, subclass 300 and 387.1, class 436, subclass 86, class 435, subclass 7.1, 320.1 and 325.
- VI. Claim 26, drawn to a method for treating lupus disorder, are classified in class 514, subclass 2<sup>+</sup>, class 530, subclass 300 and 387.1, class 436, subclass 86, class 435, subclass 7.1, 320.1 and 325.

- VII. Claims 27-28, drawn to a method for treating cardiovascular disease, are classified in class 514, subclass 2<sup>+</sup>, class 530, subclass 300 and 387.1, class 436, subclass 86, class 435, subclass 7.1, 320.1 and 325.
- VIII. Claims 29-33, drawn to an antibody, are classified in class 530, subclass 387.1.
- IX. Claims 34-36, drawn to a polypeptide comprising domains D1, D2, D3, D4, or D5 of receptor for hyaluronan-mediated motility (RHAMM), are classified in class 530, subclass, 300 and 514, subclass 2<sup>+</sup>.
- X. Claim 37, drawn to a method for treating or preventing diabetes mellitus, are classified in class 514, subclass 2<sup>+</sup>, class 530, subclass 300 and 387.1, class 436, subclass 86, class 435, subclass 7.1, 320.1 and 325.

The Examiner has also required an election of species, as follows:

- a) a single disclosed peptide must be elected.
- b) a domain of RHAMM (i.e., D1, D2, D3, D4 or D5) must be elected.

In addition, if Group I is elected, the Examiner requires a further election of species of the disorder to be treated, as follows: i) Parkinsons disease; ii) Alzheimer disease; iii) arthritis; iv) multiple sclerosis; v) inflammatory dermatosis; vi) inflammatory bowel disease; and vii) inflammatory lung disease.

Response to Restriction Requirement:

In response, Applicants elect Group I, Claims 1-10 and 21-24 and newly added Claim 38, with traverse.

MPEP §803 provides, in relevant part:

An application may properly be restricted to one of two or more claimed inventions if (a) the inventions are independent or distinct as claimed; and (b) a serious burden is imposed on the Examiner if restriction is not required. If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to independent or distinct inventions. Moreover, the Examiner must provide reasons and/or examples to support conclusions regarding a need for restriction, but need not cite documents to support the requirement in most cases.

In the present case, Applicants submit that the restriction between the subject matter directed to methods for treating various disorders is not proper or necessary and that this restriction be withdrawn. Specifically, Applicants submit that the point of novelty is the method of treatment of the claimed disorders with the enumerated compounds. The claims of Group I-VII and X are all directed to treating various disorders using a compound selected from the group consisting of (a) a polypeptide comprising the amino acid sequence BX7B which binds HA; (b) an antibody which binds one of domains D1, D2, D3, D4, or, D5 of RHAMM; (c) a polypeptide fragment which comprises at least one D1, D2, D3, D4, or, D5 domain of RHAMM; and (d) a gene delivery vector which expresses antisense RHAMM, or, delivers and expresses any one of (a), (b), or (c), such that the disorder is treated.

Accordingly, Applicants submit that a combined search of Groups I-VII and X should not impose an undue burden on the Examiner since any pertinent art relating to the methods of one group is likely to be relevant to the methods of the other groups. In fact, one would expect to find reference to each method of treatment using a compound selected from the group consisting of (a) a polypeptide comprising the amino acid sequence BX7B which binds HA; (b) an antibody which binds one of domains D1, D2, D3, D4, or, D5 of RHAMM; (c) a polypeptide fragment which comprises at least one D1, D2, D3, D4, or, D5 domain of RHAMM; and (d) a gene delivery vector which expresses antisense RHAMM, or, delivers and expresses any one of (a), (b), or (c) in the same document, regardless of the condition.

Applicants also elect, with traverse, the following species, as required by the Examiner:

a) single disclosed peptide: the D5 domain of RHAMM.

Claims 1-10, 21-24 and 38 read thereon.

b) a domain of RHAMM: D5.

Claims 1-10, 21-24 and 38 read thereon.

c) disorder to be treated: multiple sclerosis.

Claims 1 and 7 read thereon.



Application No. 09/685,010  
Attorney's Docket No. 033352-007  
Page 16

Applicants submit that a combined search of the above species should not impose an undue burden on the Examiner since any pertinent art relating to one species is likely to be relevant to the other species. In fact, one would expect to find reference to each species in the same document.

Conclusions:

In view of the above remarks, entry of the amendments, withdrawal of the requirement for restriction, in part, and/or regrouping of the claims and examination of this application on the merits are earnestly solicited.

Respectfully submitted,

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**Attachment to Amendment and Reply to Restriction Requirement dated December 11, 2002**

**Marked-up Claims 1-4, 7, 8, 10 and 21**

--1. (amended) A method for treating a patient with [a inflammatory] an inflammatory or neurological disorder, comprising administering to a patient a compound selected from the group consisting of (a) a polypeptide comprising the amino acid sequence BX7B which binds HA; (b) an antibody which binds one of domains D1, D2, D3, D4, or, D5 of RHAMM; (c) a polypeptide fragment which [encodes a] comprises at least one D1, D2, D3, D4, or, D5 domain of RHAMM; and (d) a gene delivery vector which expresses antisense RHAMM, or, delivers and expresses any one of (a), (b), or (c), such that said inflammatory or neurological disorder is treated.

2. (amended) The method according to claim 1 wherein said [inflammatory neurological] disorder is Parkinsons disease.

3. (amended) The method according to claim 1 wherein said [inflammatory neurological] disorder is Alzheimer disease

4. (amended) A method for treating a patient with arthritis, comprising administering to a patient a compound selected from the group consisting of (a) a polypeptide comprising the amino acid sequence BX7B which binds HA; (b) an antibody which binds one of domains D1, D2, D3, D4, or, D5 of RHAMM; (c) a polypeptide fragment which [encodes a]

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comprises at least one D1, D2, D3, D4, or, D5 domain of RHAMM; and (d) a gene delivery vector which expresses antisense RHAMM, or, delivers and expresses any one of (a), (b), or (c), such that said arthritis is treated.

7. (amended) A method for treating a patient with multiple sclerosis, comprising administering to a patient a compound selected from the group consisting of (a) a polypeptide comprising the amino acid sequence BX7B which binds HA; (b) an antibody which binds one of domains D1, D2, D3, D4, or, D5 of RHAMM; (c) a polypeptide fragment which [encodes a] comprises at least one D1, D2, D3, D4, or, D5 domain of RHAMM; and (d) a gene delivery vector which expresses antisense RHAMM, or, delivers and expresses any one of (a), (b), or (c), such that said multiple sclerosis is treated.

8. (amended) A method for treating a patient with inflammatory dermatosis, comprising administering to a patient a compound selected from the group consisting of (a) a polypeptide comprising the amino acid sequence BX7B which binds HA; (b) an antibody which binds one of domains D1, D2, D3, D4, or, D5 of RHAMM; (c) a polypeptide fragment which [encodes a] comprises at least one D1, D2, D3, D4, or, D5 domain of RHAMM; and (d) a gene delivery vector which expresses antisense RHAMM, or, delivers and expresses any one of (a), (b), or (c), such that said inflammatory dermatitis is treated.





Application No. 09/685,010  
Attorney's Docket No. 033352-007  
Page 3

**Attachment to Amendment and Reply to Restriction Requirement dated December 11, 2002**

**Marked-up Claims 1-4, 7, 8, 10 and 21**

10. (amended) A method for treating a patient with inflammatory bowel disease, comprising administering to a patient a compound selected from the group consisting of (a) a polypeptide comprising the amino acid sequence BX7B which binds HA; (b) an antibody which binds one of domains D1, D2, D3, D4, or, D5 of RHAMM; (c) a polypeptide fragment which [encodes a] comprises at least one D1, D2, D3, D4, or, D5 domain of RHAMM; and (d) a gene delivery vector which expresses antisense RHAMM, or, delivers and expresses any one of (a), (b), or (c), such that said inflammatory bowel disease is treated.

21. (amended) A method for treating inflammatory lung disease, comprising administering to a patient a compound selected from the group consisting of (a) a polypeptide comprising the amino acid sequence BX7B which binds HA; (b) an antibody which binds one of domains D1, D2, D3, D4, or, D5 of RHAMM; (c) a polypeptide fragment which [encodes a] comprises at least one D1, D2, D3, D4, or, D5 domain of RHAMM; and (d) a gene delivery vector which expresses antisense RHAMM, or, delivers and expresses any one of (a), (b), or (c), such that said inflammatory lung disease is treated.--

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